



Evaluating the Role of Pharmacovigilance in Ensuring the Safe Use of Mefenamic Acid

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ABSTRACT:

Mefenamic acid, a non-steroidal anti-inflammatory drug (NSAID) belonging to the anthranilic acid derivative class, is widely prescribed for the management of mild to moderate pain, inflammation, and dysmenorrhea. Despite its therapeutic benefits, post-marketing pharmacovigilance reports have highlighted severe adverse reactions, including Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) syndrome, hepatic toxicity, and hematological complications. Its act primarily by inhibiting cyclooxygenase (Cox1 & Cox2) enzymes, thereby reducing prostaglandin synthesis responsible for pain and uterine contraction. mefenamic acid exhibits good oral absorption and rapid onset of action, with extensive hepatic metabolism and renal excretion. Despite its effectiveness, use is limited by gastro intestinal irritation, renal effect and potential hypersensitivity reaction especially when used for prolonged period. Current research focuses on improving its therapeutic safety, optimizing formulation and understanding adr profile. overall mefenamic acid remains and important analgesic and anti-inflammatory agent particularly in menstrual pain management.

Keywords: Mefenamic acid, DRESS syndrome, Adverse drug reactions, NSAIDs, India Pharmacopeia Commission.

INTRODUCTION:

A type of nonsteroidal anti-inflammatory drug (NSAID) called mefenamic acid is used to treat mild to moderate pain. It is a member of the class of anthranilic acid derivatives, also known as fenamate. Its systematic term, the dimethylphenylaminobenzoic acid, is the source of this moniker. In the year 1960, Parke-Davis found it and introduced Mefenamic Acid to the market. It was made generic in the 1980s and is sold all over the world under multiple brand names, including Mefal.

Mefenamic acid is regarded as class II in the pharmacological classification procedure given its poor ability to dissolve across a pH value of 1.2–7.5. Non-steroidal anti-inflammatory drugs, or NSAIDs, are some of the most commonly prescribed and over-the-counter (OTC) medications in around the globe. Drug redness with eosinophilia and systemic symptoms, or DRESS syndrome. It represents a severe allergic reaction linked to some medicines that can be fatal in around 10% of cases. It manifests two to eight weeks after the drug is given and is characterized by internal organ inflammation, fever, skin rash, lymph nodes, and red blood cell irregularities.

Numerous cases are associated with leukocytosis being associated accompanied eosinophilia (90%) and/or mononucleosis (40%). The medicine that is causing Dressing syndrome must be withdrawn as soon as it is discovered. Indeed, it has been suggested that stopping medication earlier enhances the prognosis^{1,2}.

MEDICINAL USES:

In addition to being given for bleeding, mefenamic acid is used to treat pain and inflammation in rheumatoid arthritis and osteoarthritis, following surgery, acute pain, including back and muscle pain, toothaches, and discomfort during menstruation. Mefenamic acid and other oral medications (tranexamic acid) were just as successful as the levonorgestrel intrauterine coil in 10-year research; the same percentage of women had improved their quality of life and had not undergone surgery for severe bleeding.

Mefenamic acid has been shown to be useful for preventing premenstrual migraines. Treatment needs to start two days before the start of flow or a single day before the expected onset of the migraine pain and continue for the rest of the menstrual cycle. It is advised to take mefenamic acid with food⁴.



DRUG PROFILE:

• **Mefenamic Acid:** This non-steroidal anti-inflammatory drug (NSAID) has antipyretic, analgesic, and anti-inflammatory effects. It is frequently used for decreasing pain and inflammation brought on by a number of ailments, including as pain during periods and muscular disorders.

Chemical Structure: Mefenamic acid is a derivative of anthranilic acid's chemical structure and is chemically defined as N [(2,3 dimethyl phenyl)] amino] benzoic acid, for short.

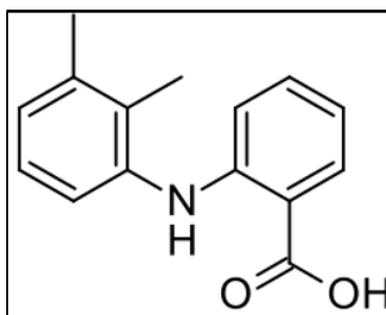


Figure 1. Structure of mefenamic Acid^{2,4}

• **Mechanism of Action:** Mefenamic acid reduces the activity of cyclooxygenase (COX) enzymes, particularly COX-1 and COX-2, thus delivering its medicinal properties. Prostaglandins, which are mediators of pain, inflammation, and fever, happen less often as an outcome of this reduction⁴.

• Pharmacokinetics:

1. Absorption: After oral dosage, mefenamic acid is well taken.
2. Metabolism: It is primarily broken down by CYP2C9 in the liver, which produces metabolites that are active.
3. Elimination: A tiny portion if the drug and its metabolites disappear in the faces, but the majority were eliminated through the urinary system.
4. Indications: Mild to moderate pain relief. treatment for periods pain, or primary dysmenorrhea. Management of musculoskeletal disorders.
5. Dosage Forms: Mefenamic acid can be taken oral in a variety of various forms, like pills and capsules.
6. Adverse Effects: Headache, nausea, vomiting, and gastrointestinal distress were typical side effects. Cardiac events, inflammation, and bleeding from the stomach are some of serious side effects.
7. Contraindications: Previous exposure of mefenamic acid or other NSAID reactions. Previous gastrointestinal bleeding or perforation. Severe liver or kidney harm. Pregnancy's third trimester.
8. Drug Interactions: Mefenamic acid can raise the risk of bleeding and kidney problems if used alongside anticoagulants, antiplatelet medicines, angiotensin-converting enzyme (ACE) inhibitors, and diuretics.
9. Cautions and Warnings: Increasing likelihood of cardiovascular incidents. risk of intestinal ulcers and bleeding. fluid retention with renal impairment. Pregnancy is contraindicated, particularly in the third trimester¹.

Mefenamic Acid Alert information:

Mefenamic acid-induced toxicity appears as a severe drug reaction with notable clinical features, such as rash, fever, lymphadenopathy, hematological abnormalities, and tissue involvement. It is especially associated with Drug Rash with Eosinophilia and Systemic signs (DRESS) syndrome. Since the situation may be life-threatening, prompt & careful healthcare is needed. The



India Pharmacopoeia Commission (IPC) made an important move on December 7 by releasing a medication safety alert that addressed the issues surrounding mefenamic acid. One frequently used non-steroidal anti-inflammatory medication (NSAID) that has been linked to problems that result in DRESS disease is the drug mefenamic acid. The importance of addressing and reducing any potential hazards linked to the use of mefenamic acid is made explicit by IPC's publication of this notice.

This regulatory communication is an important warning to medical practitioners, stressing the importance of increased awareness, timely diagnosis, and suitable therapy in situations that may be connected to DRESS disorder or mefenamic acid-induced toxicity. By increasing knowledge of the possible dangers connected to mefenamic acid, the IPC notice supports ongoing efforts to improve the safety of medications and health for all by empowering medical professionals to make well-informed decisions regarding patient care⁷.

Table 1. Regulatory Bodies Involved in Specific Ban of Drugs⁷:

Sr.no.	Regulatory Bodies	Abbreviation	Countries
1.	FDA	Food and Drug Administration	United State
2.	EMA	European Medicines Agency	European Union
3.	TGA	Therapeutics Goods and Administration	Australia
4.	CDSCO	Central Drugs Standards Control Organization	India
5.	NAM	National Agency for Medicines	Finland
6.	BfArM	Federal Institute Drugs and Medical Devices	Germany
7.	WHO	World Health Organization	Switzerland

General Procedure Involves in Ban of Drug:

In India, the final authority to impose a ban is the Drug Technological Advisory Committee (DTAB). An executive committee investigates the drug's adverse outcomes and submits the findings to the DTAB. The government issue a ban order and requests that each of the producers and importers refrain from carrying any medication which turns out to have dangerous negative effects. The DCGI notifies producers, pharmacist associations, and all state drug agencies of the substance's ban. Authorities have been told to make inspections.

Countries with population of approximately four million, 33 million, and 57 million, respectively, are Ireland, Switzerland, and Italy. The Drug and Cosmetics Act permit pharmacists who carry prohibited medicine to have their licenses revoked; however, officials at the Drug Controller of India (DCGI) office took a different stance on this issue. Over 79 categories of formulations have been outlawed thus far in the ongoing process of screening for hazardous or illogical medicinal products. Package is now standardized in order to guarantee proper shipment and responsible application of medications.

Pharmacovigilance, post-marketing surveillance, along with information from other nations are used to continually evaluate a drug's security and effectiveness even after it has been approved for sale. India has provided 25, 33, and 225 negative reactions to drugs about Nimesulide, making a contribution to the global data collection on the side effects for different medications worth noting. Despite this, India sells prescriptions like nimesulide phenyl propanolamine, heroin, etc. Interest groups in India oppose such action when a very successful substance is prohibited outside due to its negative consequences^{7,8}.

**Table 2. List of Combination Banned⁷:**

Sr.no.	Drug Combinations
1.	Mefenamic Acid + Paracetamol (injection)
2.	Omeprazole Magnesium + Dicyclomine HCl
3.	Cetirizine HCl + Paracetamol + Phenylephrine HCl
4.	Levocetirizine + Phenylephrine HCl + Paracetamol
5.	Paracetamol + Chlorpheniramine Maleate + Phenylpropanolamine
6.	Amoxicillin + Bromhexine
7.	Diclofenac + Tramadol + Paracetamol
8.	Rosuvastatin + Clopidogrel + Aspirin
9.	Nimesulide + Paracetamol (dispersible tablets)
10.	Amoxicillin + Bromhexine
11.	Pholcodine + Promethazine
12.	Chlorpheniramine maleate + Dextromethorphan + Guaifenesin + Ammonium chloride + Menthol
13.	Chlorpheniramine Maleate + Codeine (syrup)

REASONS FOR BAN:

1. Lack of therapeutic justification: Expert committees found that many FDCs lack a scientific rationale for combining ingredients.
2. Increased side effects: Combining multiple drugs can increase the risk of adverse drug reactions and make it harder to identify which ingredient is responsible.
3. Antimicrobial resistance: The irrational use of antibiotic FDCs, particularly when not all constituents are necessary, can contribute to the development of drug-resistant bacteria.
4. Safety and efficacy concerns: Many FDCs were approved without conducting comprehensive clinical trials, which may threaten the health of the public^{3,8}.

CASE REPORTS:

Case 1: In the case inquiry, a three-year-old boy was hospitalized for two days to treat chills, discipline, and irregular fever. The fever had temporarily reduced by treatment with a mixture of mefenamic acid and paracetamol, but the subsequent development of dark-colored urine aroused concerns. A previous urinary tract infection at the age of two was noted in the medical history, and there was no unusual family history of immunological or hematological conditions. A clinical examination found some temperature, mild pallor, and icterus signals. An examination of the abdominal showed an enlarged liver 3 cm below the right costal boundaries, although the spleen was not palpable. Vital signs were within the normal range. All systemic checks were unremarkable, with the exception of the urine problems. A high total leukocyte count (27,300), a hemoglobin content of 5.5, and a packed cell volume (PCV) of 17.2% had been among the aberrations found by laboratory analysis. A differential leukocyte count reported 7% lymphocytes and 70% neutrophils. Reticulocyte count was elevated at 13%, and the total platelet count was 1.51 lakh. Absolute neutrophilia, leukocytosis, and dimorphic anemia were noticed.

Case 2: The 47-year-old man in the case studies has been taking mefenamic acid for gouty arthritis since 1975. The patient's medication history indicates the dosage of mefenamic acid was gradually reduced over time, amounting to about 4,200 capsules. Other noteworthy medical history includes the development of hypertension, the recent onset of hematuria in May 1985, and left renal calculus surgery in 1977. Tests performed in the lab showed slightly high urea (7.8 mmol/l), elevated creatinine (200 pmol/l), elevated uric acid (580 pmol/l), and hemoglobin levels within the normal range (12.5 g/dl). Ten leukocytes, two or more proteins, and 26,000 red blood cells per liter were found in the urine.

Case 3: The case involves a 58-year-old woman who presented in December 1984 with recurrent, one-month long episodes of hematuria. She has a history of hypertension for almost a decade and has been using mefenamic acid (500 mg) capsules for the past two years, totaling approximately 1,000 capsules, to manage osteoarthritis in both knees. The patient denies using any additional painkillers and has no history of diabetes or tuberculosis.



Laboratory investigations revealed a hemoglobin level of 12.9g/dl, urea of 7.4mmol/l, creatinine of 120pmol/l and uric acid of 424mol/l. Urinalysis showed no organisms on culture, absence of leukocytes, epithelial cells or casts and a minimal amount of protein. The aspirin ferric chloride urine test was negative. Intravenous urogram (IVU) revealed bilateral papillary necrosis (103 g/ml).

Case 4: An 18-year-old student that had a generalized convulsion and was admitted to the hospital's casualty department is the center of the case. Symmetric tonic-clonic actions were displayed by the patient, which may indicate sympathetic hyperactive. A blood pressure of 140/90 mmHg, a sinus rhythm pulse rate of 130/min, and a nasopharyngeal temperature of 36.5°C had been important clinical data. Methylene blue, on the other hand, was found after an intravenous line was created and blood was analyzed for toxicological analysis. The first intervention was injecting 20 mg of etomidate after supplying 80 mg of diazepam intravenously and delivering 100% oxygen via a face mask. An endotracheal tube was placed after the throat and voice chords were treated with a topical 4% lignocaine solution.

20 mg of etomidate was administered intravenous as a second dose. Once a nasogastric tube was put in for gastric aspiration, 30 g of activated charcoal and 40 g of sodium sulphate were inserted into the stomach at intervals of ten minutes each. Then the patient was taken to the critical care unit, continuous positive airway pressure breathing was started. Vital signs were continuously monitored after diazepam was given for sedation and pancuronium was used for muscle relaxation. A chest radiograph revealed no cardiac or pulmonary abnormalities, arterial blood gas estimates indicated normal oxygenation, and a urine catheter was placed to track renal function. A low serum potassium level of 3.1 mmol/l was found by laboratory testing. A thorough reaction to a toxicological emergency is reflected in the entire treatment strategy, which includes breathing assistance, digestive tract purification, and ongoing monitoring. For the best possible patient care and wellness, regular monitoring of vital signs, renal function, and potassium levels is essential. The presence of methylene blue in the blood may be particular exposure or poisoning, justifying more studies into the underlying cause.

Case 5: In the investigation, a 24-year-old man went to the hospital after a car accident that caused injuries consisting of a closed fracture of the right proximal shaft and a separation of the left distal femoral epiphysis (Salter II fracture). The left lower limb was placed in a plaster cast after the epiphyseal fracture was reduced. Seven days later, open reduction and intramedullary fixation with a nail were implemented to treat the right femur fracture. Compression dressings were utilized to control the patient's small bleeding episodes noticed on the tenth and sixteenth postoperative days. However, the patient showed up with significant bleeding from the right leg on the evening of the 21st postoperative day. 1.5 liters of blood were administered, and a tight compression bandage was placed around the thigh to achieve hemostasis. Examines for a clotting disorder yielded negative results and the distal vascular supply to the foot normal. Additionally, there was no localized swelling in the right thigh⁵.

Table 3: Different Brands of Mefenamic Acid Present in Market (Single brands)⁹:

Drugs	Manufacturers
Meftal	From Blue Cross Laboratories Ltd.
Ponstan	From Pfizer Ltd.
Mefkind	From Mankind Pharma Ltd.
Macfast	From Macleods Pharmaceuticals Pvt Ltd.
Pacimol MF	From Ipca Laboratories Ltd.
Dolopar M	From Micro Labs Ltd.
Meftagesic	From Blue Cross Laboratories Ltd.
Meftal-Forte	A stronger version of Meftal, also from Blue Cross Laboratories Ltd.
Meftal-SPAS (A combination of mefenamic acid and dicyclomine hydrochloride)	From Blue Cross Laboratories Pvt Ltd.
Mefanorm	From Serum Institute of India Ltd.
Febrinil M	From Maneesh Pharmaceuticals Ltd.
Mefast	From Zuventus Healthcare Ltd.



Combination brands:

1. Mefenamic Acid + Paracetamol: Brands like Meftal-P, Mefkind-P, and Mysafe-P combine mefenamic acid with paracetamol to treat pain and fever.
2. Tranexamic Acid + Mefenamic Acid: Brands like StayHappy Tranexamic Acid+Mefenamic Acid and Trenaxa MF combine mefenamic acid with tranexamic acid to treat heavy menstrual bleeding and pain.
3. Drotaverine + Mefenamic Acid: Brands that combine mefenamic acid with drotaverine are used to relieve abdominal pain.
4. Mefenamic Acid + Dicyclomine Hydrochloride: Brands like Macspas contain mefenamic acid and dicyclomine hydrochloride for conditions like irritable bowel syndrome⁹.

Meftal Spas is a combination medication that typically contains:

1. Mefenamic Acid: It is a non-steroidal anti-inflammatory drug (NSAID) that helps reduce pain, inflammation and fever.
2. Dicyclomine: This is an antispasmodic that works by relaxing smooth muscles in the gastrointestinal tract. It can help alleviate muscle spasms and cramps. Meftal Spas is commonly prescribed for conditions such as menstrual cramps (dysmenorrhea) and abdominal pain associated with irritable bowel syndrome.
3. Ponstan: Ponstan is a brand name for a medication that contains mefenamic acid as its active ingredient. Mefenamic acid is a nonsteroidal anti-inflammatory drug (NSAID) commonly used to relieve pain, inflammation, and fever. It's often prescribed for conditions like menstrual pain, mild to moderate pain and certain types of arthritis. It's commonly used to alleviate pain and inflammation associated with conditions like menstrual pain, mild to moderate pain, and certain types of arthritis.
4. Mefacid: Mefacid 500mg Tablet is a common painkiller used to treat aches and pains. It blocks chemical messengers in the brain that tell us we have pain. It is effective in relieving pain caused by headache, migraine, nerve pain, toothache, sore throat, period (menstrual) pains, arthritis and muscle aches.
5. Gefplus: This Tablet contains mefenamic acid and paracetamol as its active molecules. It works by reducing the formation of certain chemicals that causes the sensation of pain. This Tablet is also useful in treating pain due to sprain, strain and injury, post-operative pain and dental pain⁷.

Availability Of Banned Drug in India:

1. Oxyphenbutazone: Oxyphenbutazone, a metabolite of phenylbutazone, is an NSAID. It has been used for episcleritis, osteoarthritis, and rheumatoid arthritis etc. the severe adverse effects of oxyphenbutazone, which provide upward thrust to in addition headaches encompass allergic reactions, stomach pain, blurred vision.
2. Metamizole: Metamizole (Dipyrone) belongs to a collection of drugs that eliminate pain and reduce fever. Metamizole can cause damage to the bone marrow (granulocytopenia, agranulocytosis, hemolytic anemia, aplastic anemia.), digestive problems etc.
3. Cisapride: Cisapride is a "PROKINETIC AGENT" that used for treatment of gastroesophageal reflux disease (GERD). There is no proof it's miles powerful for this use in children, proof for its use in constipation is now no longer clear. It has been found to cause cardiac arrhythmias (abnormal coronary heart rhythms).
4. Cerivastatin: Cerivastatin prevents the risk of stroke and coronary heart attack it functions with the aid of using blocking away the enzymes in the liver that is responsible in the production of cholesterol inside the body. There is numerous facet consequences related with the aid of using the use of CERIVASTATIN, for example- diarrhea, nasal congestion, constipation, headache and heartburn, muscle damage, sexual problems, fever, issue in respiratory etc.
5. Droperidol: Droperidol is an Antidopaminergic drug used as an antiemetic and antipsychotic. It also regularly used for neuroleptanalgesia anesthesia and sedation in intensive-care treatment, but it causes dysphoria, sedation, hypotension resulting from peripheral alpha adrenoceptor blockade, prolongation of programming language which can lead to extra pyramidal facet consequences together with dystonic response disorder, uncontrollable muscle movements of your lips.



6. Nimesulide: Nimesulide is a non-steroidal anti-inflammatory drug, used for painful inflammatory conditions, back pain, dysmenorrhea, postoperative.

7. Furazolidone: Furazolidone is a Nitrofurantoin Antibacterial. It is marketed under the brand name furaxan, furazolidone has been used in human and veterinary medicine. In humans it has used to deal with diarrhea and enteritis caused by microorganism or protozoan infections. It has been used to deal with cholera and bacteremic salmonellosis, and helicobacter pylori infections, it has many side effects, and as with different nitro furans generally, minimum inhibitory concentrations additionally produce systemic toxicity (tremors, convulsions, peripheral neuritis, gastrointestinal disturbance, depressions of spermatogenesis).

8. Nitrofurazone: Nitrofurazone is bactericidal for maximum pathogens that usually move floor pores and skin infections. Topical nitrofurazone is indicated as an adjunctive therapy second and third-degree burns. The unfavorable consequences had been decided the idea in their ability medical significances itching, rash and swelling.

9. Thioridazine: Thioridazine is an antipsychotic medicinal drug known as a phenothiazine. It is used to deal with schizophrenia. But it can move a life-threatening coronary heart rhythm pain, osteoarthritis and fever. Caution should be exercised in sufferers with records of belly problem, high blood pressure, fluid retention, stomach discomfort, heartburn, stomach cramps, nausea, vomiting, diarrhea, headache, dizziness and drowsiness, blood in urine and kidney failure⁸.

Table 4: Drugs With Their Use and Reason of Withdrawal ⁶:

Drugs	Uses	Reason of Withdrawal
Metamizole (Analgin)	Analgesic	Agranulocytosis
Oxyphenbutazone	Analgesic	Bone Marrow Depression
Nimesulide	Analgesic	Liver Toxicity
Furazolidone	Antidiarrheal	Risk of Cancer
Nitrofurazone	Antidiarrheal	Risk of Cancer
Cerivastatin	Dyslipidemia	Rhabdomyolysis
Phenolphthalein	Stimulant Purgative	Risk of Cancer
Quiniodochlor	Amoebicidal	Subacute myelo-optic Neuropathy
Thioridazine	Antipsychotic	Arrhythmia
Pergolide	Parkinsons Disease	Damage to heart valve
Droperidol	Antidepressant	Cardiac Arrhythmia (Irregular heartbeat)

CONCLUSION:

The increasing amount of Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) syndrome related to certain medicines is highlighted in regulatory agency studies and literature reports. A specific medication linked to DRESS syndrome is still sold over-the-counter in India despite regulatory warnings about its known side effects. This study provides useful consumer information about the continued presence of prohibited pharmaceuticals in the market by synthesizing data from the literature. Significant public health concerns are raised by the observed unlawful sale of these medicinal products as over-the-counter remedies in India, including the one under regulatory alert. In addition to identifying the urgent need for regulatory action, the literature review lays out the basis for more study. This study's detailed overview of the existing situation and simple use make it a beneficial instrument for future investigations. This literature review can be expanded upon in future research tasks, using its findings to confront the problems caused by the accessibility and abuse of banned chemicals in the Indian market.

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